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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/619,901	07/19/2000	Michael J. Botich	1032-P00101US9	2085

110 7590 12/01/2004

DANN, DORFMAN, HERRELL & SKILLMAN  
1601 MARKET STREET  
SUITE 2400  
PHILADELPHIA, PA 19103-2307

EXAMINER
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WILLIAMS, CATHERINE SERKE

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/619,901

**Applicant(s)**

BOTICH ET AL.

**Examiner**

Catherine S. Williams

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 45-46, 48-52, 54-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45-46, 48-52, 54-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The terminal disclaimer filed 3/2/04 is being entered into the record. The double patenting rejection of 6,179,812 has been withdrawn.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 45, 48-50, 69 and 72 rejected under 35 U.S.C. 102(e) as being anticipated by Ridderheim et al (US Pat# 4,955,870).

Ridderheim discloses a medical device having a needle (12) operable between a projected position and a retracted position (see figures 9a-9e), a hollow barrel (10), a plunger (14) with a cavity and a cover (see distal end of the plunger 14, figure 2), and a biasing spring element (56). The biasing element biases the needle toward the retracted position when the cover on the plunger has been severed by moving into an end position and contacting the needle housing. See figure 9e. Once the cover has been severed the needle and spring are retracted into the cavity of the plunger. "In this position, needle 12 and the sharp end 62 thereof are located within duct 52 of plunger 14 and out of the way so as to prevent accidental puncture with the contaminated needle 12". See 8:32+. The device also includes a first and second threaded mated connectors (see figure 2 and 3) for attaching the needle to the barrel.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45-46, 48, 50-54, 56-58, 60-64 and 66-73 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-16 of U.S. Patent No. 4,994,034. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application and the above patent both claim a barrel with a first connector (barrel means), a needle assembly with spring and second connector (spring holding means) that engages the first connector and a plunger with a cavity and a breakable end that is severed with the plunger is depressed into the bottom of the barrel. Further, both further claim a needle retainer with fingers which are spread by the plunger to release the needle. Claim 16 of the above patent claims that the spring holding means "can easily be attached and removed from the barrel means" (releasably connected: claim 54 of instant application). The method steps are inherent to the claims of the above patent.

Claims 45-47, 50-53, 56-59, 61-64 and 67-73 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 23 of

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U.S. Patent No. 5,407,431. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application and the above patent both claim a barrel with a first connector (barrel means), a needle assembly with spring and second connector (spring holding means) that engages the first connector and a plunger with a cavity and a breakable end that is severed with the plunger is depressed into the bottom of the barrel. Further, both further claim a needle retainer with fingers which are spread by the plunger to release the needle. The method steps are inherent to the claims of the above patent.

Claims 45-46, 49-52 and 55-73 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,188,599 in view of Alter et al (4,919,652). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application and the above patent ('599) both claim a barrel with a first connector (barrel means), a needle assembly with spring and second connector (spring holding means) that engages the first connector and a plunger with a cavity and a breakable end that is severed with the plunger is depressed into the bottom of the barrel. Further, both further claim a needle retainer with fingers which are spread by the plunger to release the needle. The method steps are inherent to the claims of the above patent.

The claims of the instant application are unpatentably similar to the patent as described above. While the above patent does not claim that the "means" for connection is a threaded connector, one is considered obvious. The above patent ('599) shows and discloses a push/frictional connection between the needle assembly and the barrel of the syringe. See figures. However, it would have been obvious to substitute the push/frictional connection of the

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above patents with a threaded connector. Threaded connectors are well known in the art for attaching needle assemblies to syringe barrels. Alter et al discloses such a connection.

Additionally, the needle assembly of Alter, once threaded into the barrel, protrudes into the interior of the barrel much like the needle assemblies of the above patents. The motivation for the substitution would have been to use a well-known mechanism of needle attachment.

Claims 49, 55, 59 and 65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-16 of U.S. Patent No. 4,994,034 in view of Alter et al (4,919,652).

Claims 49, 55 and 65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-16 of U.S. Patent No. 5,407,431 in view of Alter et al (4,919,652).

Claims 49, 55, 59 and 65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,188,599 in view of Alter et al (4,919,652).

The claims of the instant application are unpatentably similar to the patents as described above. While the above patents do not claim that the "means" for connection is a threaded connector, one is considered obvious. The above patents show and discloses a push/frictional connection between the needle assembly and the barrel of the syringe. See figures. However, it would have been obvious to substitute the push/frictional connection of the above patents with a threaded connector. Threaded connectors are well known in the art for attaching needle assemblies to syringe barrels. Alter et al discloses such a connection. Additionally, the needle

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assembly of Alter, once threaded into the barrel, protrudes into the interior of the barrel much like the needle assemblies of the above patents. The motivation for the substitution would have been to use a well-known mechanism of needle attachment.

### *Response to Arguments*

Applicant's arguments filed 9/24/04 have been fully considered but they are not persuasive. Regarding Ridderheim applicant argues essentially that since Ridderheim shows a biasing element within the plunger of the device the spring cannot be considered part of the needle assembly. However, the claim language regarding the needle assembly is broad and does not impart any structural limitations on the components of the needle assembly other than claiming multiple elements as a needle assembly. The spring is part of the needle assembly in that the spring acts on the needle to retract the needle after use. Therefore, the spring is part of the needle assembly. Applicant further argues that the needle assembly can be attached to the barrel prior to use. However, this language is not contained in the rejected claims. Applicant also points to "disadvantages" of the Ridderheim reference; however, these arguments are moot since Ridderheim meets the structural limitations of the instant claims.

Regarding the doubling patenting rejection of the '599 reference, as long as the prior patent claims meet the limitations of the instant claims then the double patenting rejection is proper. Additional limitations and differences of the prior patent are moot as long as the prior patent has all, or renders obvious all, the limitations of the instant claims. Regarding the arguments that the prior patent does not have the connectors of the instant claims, the double patenting rejection was changed above to render the connectors obvious.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

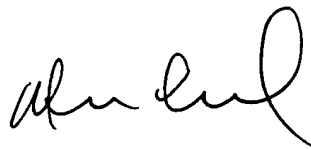
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams *CSW*.  
November 24, 2004

  
**NICHOLAS D. LUCCHESI**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 3700**